Russian Medical Equipment Market
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This report reviews the Russian medical equipment, devices and supplies market and analyzes the opportunities for U.S. manufacturers and suppliers in this market.

Market Overview

Russia is a large country with a population of 145.2 million people. However, only one fifth of the population has access to quality healthcare. Russia has a vast healthcare network, which includes 9,663 in-patient hospitals, 16,615 out-patient polyclinics, and 3,252 emergency stations. Further, Russia has 608,588 doctors and 1,388,349 paramedics. Most of the hospitals and polyclinics are public and belong to federal or regional governments (Russia consists of 89 regions). There is also a significant number of so-called agency healthcare establishments belonging to specific large governmental structures such as Ministry of Transportation, Ministry of Economic Development and Trade, Ministry of Defense and so on. The share of private clinics is less than 3 percent and they are mostly represented by dental, eye, and cosmetology clinics.

A significant portion of the medical equipment and devices used in public clinics and hospitals is worn and needs replacement. Russia still does not produce many types of high-end medical equipment and relies on imports of such equipment. Opportunities in the market are vast, however financing is scarce and insufficient. Total public healthcare spending in Russia at all levels comprises only 3.7 percent of the GNP.

In the last three years the Russian medical equipment and devices market has shown substantial and steady growth with annual rates exceeding 10 percent. The total volume of the market in 2003 is estimated at 1.4 billion dollars. Imports play a significant role accounting for about 75 percent of the total market.

Domestic production received a significant boost after the 1998 economic crisis when a number of local manufacturers, having taken advantage of the sharp rise in the price of imported medical equipment, managed to increase their share in a number of market segments. Russia has achieved significant progress in several traditional and a number of developing segments of medical equipment manufacturing, such as electrocardiographs, patient monitors, X-Ray and fluorography devices, anesthesia, sterilization and pulmonary equipment, ultrasound scanners, devices and instruments for endoscopy and laparoscopy, as well as electrosurgical instruments. Stronger domestic positions were also achieved in emergency vehicles, operating lighting systems, surgical instruments, home healthcare products, orthopedic devices, ophthalmic products, test kits, polymeric and glass medical products, disposable syringes, IV solutions and sets and other disposables.

Russian production still lags behind the majority of developed countries in the medical equipment industry subsectors and is lacking a large R&D component, use of innovative technologies, and automation. Such industry subsectors include modern computerized diagnostic equipment, computer and X-Ray tomographs, angiography systems, resuscitation and functional diagnostic equipment, implants and prostheses, robotics clinical laboratory systems for express microanalysis, telemedicine complexes, hospital equipment and supplies, operational room equipment, artificial kidney complex components (oxigenerators and dialyzers), hospital beds, as well as advanced home healthcare equipment and supplies and a significant amount of medical supplies and disposables, including polymeric packaging for IV solutions, are imported.

Market Trends

Russia has been experiencing 7 percent annual economic growth over the last two years, which resulted in significant improvement of business activity and an increase in the purchasing power of the population. At the same time, inflation has been quite high and will, according to estimates, reach 10 percent in the current year. Other negative factors include an underdeveloped private healthcare insurance system, small middle class, high differentiation of incomes, a low disease prevention culture, and a high unemployment rate. As for positive factors affecting growth of imports from the United States versus Europe, there has been a decreasing ruble-dollar exchange rate followed by a large and growing ruble-euro exchange rate making imports from European countries more expensive. The ruble-dollar exchange rate for 2004 is estimated at 29.8 rubles per dollar while the ruble-euro rate: is 36 rubles per euro.

An important promising development is the current reform of the health insurance system. At the moment, the major two state sources of healthcare funding - Mandatory Insurance Funds (40 percent of total funding) and spending supported by federal and regional budgets (60 percent) – do not cover healthcare expenses. Private healthcare insurance programs' coverage is approximately 5 percent. As a result, about 50 percent of the total healthcare costs, according to official data, are paid for out-of-pocket.

The government plans to submit to the Parliament a new law on healthcare insurance, which is designed to restructure the healthcare system through streamlining healthcare financing and increasing its efficiency. Currently, the existence of multiple funding channels has led to the duplication of payments for the same medical procedure and significant waste. The new law is designed to transfer all the funding to one source – Mandatory Insurance Funds, which will provide transparency and control over cash flow within the system. However, there are no clear-cut explanations on how the government plans to increase total revenues for the Mandatory Insurance Funds to cover necessary healthcare spending. A recent decrease of the unified social tax from 3.6 to 2.8 percent may only aggravate the situation. It is obvious that the government plans to shift the burden of the healthcare costs to the population through development of private insurance.

Further, Russia still does not have a developed legislative basis for the medical device

and equipment market. The Law on Medical Equipment and Devices has been discussed for several years in the Duma, the lower chamber of the Russian Parliament, but has not been adopted. Importation, registration, conformity assurance, and licensing of medical devices are governed by a number of regulatory norms, often arbitrary and contradicting, which are issued by departments of various ministries (Ministry of Health and Social Development, Standards agency, Customs service, Tax service). No clear-cut regulation exists for in-vitro medical devices.

Also, there is no unified definition of medical devices. Instead, medical devices are arbitrarily grouped by different government agencies into devices, equipment, instruments, items of medical use, etc. This leads to the absence of unified regulations affecting different aspects of the medical equipment business such as VAT rates, charges and registration expiry dates. As tax and customs codes for medical devices do not comply with each other, VAT rate is set arbitrarily and can vary from 0 to 20 percent.

Import Market

Reliable statistical information on the medical equipment market for 2003 is not available. Therefore, the 2003 figures are estimates made by the author. The sources for statistical information for 2002 are as follows: Federal State Statistics Committee, Federal Customs Committee and Russian Scientific and Research Institute for Medical Industry. The Russian market for medical equipment and supplies in 2003 is estimated at 1.4 billion dollars. Imports comprise about 1 billion, or 75 percent of the total market. Exports of medical equipment from Russia are estimated at 40 million dollars. Imports from the United States are estimated at 190 million dollars. In 2002 the total market was 1.24 billion, imports – 900 million and total exports – 34 million, while imports from the United States are estimated at 180 million dollars.

In general, imported medical equipment and supplies still play a predominant role accounting for 75 percent of the total market. For example, foreign-made high-end medical equipment with a large R&D component, sophisticated medical devices, and many medical products and supplies do not have Russian produced substitutes. According to the author's estimates, German suppliers play a key role in the import market accounting for 46 percent of the total imports. The United States' share is 22 percent, significantly lower than German, but ranking second in the total import market. Other major suppliers include Japan (9 percent), Italy (5 percent), and France (5 percent). U.S. medical equipment and devices are generally in high demand.

Competition

Key competitors to U.S. medical equipment companies are European and Japanese suppliers. These suppliers mainly compete in the advanced state-of-the–art and innovative products segments. In some traditional segments, which were mentioned above, local manufacturers present significant competition to the foreign suppliers.

In Russia, medical equipment and devices are manufactured at 1,500 enterprises having

federal licenses for the production of medical equipment and devices. The leading role is played by 32 specialized medical device enterprises controlling 42 percent of the total output, and 200 defense plants accounting for 12 percent of the total output. In addition, about 800 small and medium-sized enterprises hold 30 percent of total domestic production. Approximately three percent of the total medical equipment and device output is concentrated at enterprises belonging to the Federal Agency on Atomic Energy. A significant portion of high-tech medical equipment is still developed and produced at defense enterprises, which have traditionally had access to advanced technologies.

European companies use aggressive techniques to penetrate the Russian market by participating in major local healthcare trade shows and industry-specific medical conferences. In many cases, European governments provide financial support to their companies for arranging national pavilions at major healthcare and dental events in Russia. It has become common practice for European manufactures to register subsidiary companies in Russia with a right to be involved in commercial activities and with a possibility to oversee the local business operation directly and establish better control over distributors and agents. These companies handle importation, customs clearance, registration and warehousing of the products themselves and often work with local distributors and agents on a consignment basis.

End Users

The main end-users of medical equipment are clinics and hospitals which for the major part are public. In the last ten years a number of independent private clinics (mostly dental, ophthalmic and cosmetology) and stand alone clinical laboratories were established, predominately in large cities. Private clinics are completely self-financed.

Funding for medical equipment, devices and supplies purchases for public healthcare establishments comes from two major sources: federal and regional mandatory insurance funds and federal and regional budgets. Mandatory insurance funds mainly cover purchases of small medical devices, supplies and disposables. According to the official statistics of the Federal Mandatory Insurance Fund, in 2003 less than 6 percent of the total Fund's expenses went to purchase medical equipment and durable goods for hospitals and polyclinics.

The purchase of expensive medical equipment is usually financed by federal and local health budgets. The role of the federal government in financing medical equipment purchases has diminished significantly while the role of local governments has increased. Local government finances support 97 percent of the purchases of medical equipment and supplies, while the federal government finances 3 percent. Generally, public funding for purchasing medical equipment and supplies for hospitals and clinics is insufficient. According to the Audit Chamber of Accounts of the Russian Federation, public hospitals and clinics are only able to procure 30-40 percent of the medical equipment and supplies they require to operate.

According to the law, medical equipment with a cost of less than 200,000 rubles ($7,000)

can be sold directly to hospitals without tenders. Purchases of expensive equipment are normally done through tenders. In some cases, where unique expensive medical equipment is involved, it may be procured without tenders upon approval of the Ministry of Health and Social Development. Tenders are normally arranged by local healthcare authorities. The list of tenders is published on a regular basis in Competitive Bids magazine (www.bob.ru).

Key decision-makers in the purchasing of medical equipment are the heads of hospitals that coordinate their activities with heads of local healthcare administrators controlling the regional healthcare budgets. Suppliers of medical equipment have to be aware that many medical equipment deals include commissions to such individuals.

The decision-making process for purchasing specific types of medical equipment is as follows. As a rule, in small and medium-size hospitals head doctors are the only decision-makers. In large, diversified hospitals, heads of departments are also involved. Distributors handling sophisticated new high-end equipment place emphasis on working with doctors directly by organizing training seminars, site visits, etc. In the regions, distributors work either directly with the hospital heads or through networks of regional agents. To encourage doctors to use imported devices in their practice, distributors of Western manufacturers have to pay commissions to doctors who prescribe such devices to their patients. Commissions to doctors are in many cases camouflaged under different fees such as consulting fees.

Market Access

Current Russian legislation is not a significant barrier to importers of medical equipment. Customs duties for the majority of these products are currently 5 percent. Exceptions concern IV sets and disposable syringes for which customs duties are 15 percent. Jacuzzi baths and medical thermometers are subject to 10 percent customs duty. Most types of equipment are VAT-exempt. The major non-tariff barriers include registration and certification of medical equipment and supplies.

Despite positive changes in the past several years, Russia still relies on product testing as a key element in the medical product approval process. Other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance, are underdeveloped. Russia adheres to redundant practices of further testing of FDA-approved and CE-marked medical equipment and devices which delay entry of advanced medical technologies into the country. In addition, cultural and language barriers could become a challenge to foreign companies attempting to register medical equipment by themselves without appropriate legal advice or assistance from experienced distributors or consultants.

The registration procedure for medical equipment and supplies includes several stages. The applicant must submit the necessary documents to the Federal Service for Surveillance in Healthcare and Social Development Sector for review. Next, the applicant will receive a list of tests the product must undergo, including technical,

toxicology, hygienic, clinical and other. Actual tests are conducted by a number of expert institutes, laboratories and clinics. The above mentioned organizations do not have clearly defined, standard operating procedures, which makes the process lengthy and biased. The fees for the trials are in most cases negotiated on a case-by-case basis. As for the duration of tests, they often last more than three months. Upon completion of the tests the company receives protocols which are submitted to the Service for final approval and issuance of a registration certificate. As soon as the device is registered, it is entered into the State Registrar of Medical Devices and Equipment. The duration of the entire registration procedure make take from 6 months to a year. The term for registration certificates for medical equipment, devices, instruments, plants, and medical furniture is 10 years, and for medical supplies, including reagents and disposable items, 5 years.

Imported medical equipment and devices should conform to Russian quality and safety standards, which are set by the Federal Agency for Technical Regulations and Metrology (Gosstandart). The Agency ensures product conformity through a system of end product certifications. It authorizes a number of national and several international testing institutes and centers to issue safety and quality certificates, or GOST R certificates. Safety certificates requested by manufacturers of medical devices usually are issued for longer terms, up to three years. Certificates sought by distributors or trading companies are usually issued for shorter terms, up to one year.

Medical equipment and devices are subject to mandatory duplicate testing and certification by the Ministry of Health and Social Development and the Federal Agency for Technical Regulations and Metrology. In order to obtain the above certificates, the company must conduct product tests, which are practically identical, twice. As a result, the company incurs additional unnecessary costs. Above all, serial certification of medical equipment and devices involves the travel of Russian standards experts to foreign production sites, the cost of which is born by the manufacturer.

The GOST R certificate and the registration certificate are the two major documents reviewed by customs authorities when goods cross the country's borders.

Market Entry

In Russia hospitals and clinics are not directly involved in importing medical equipment and supplies. Imported medical equipment is brought to the country mainly through distributors. Distributors in most cases also sell medical equipment to end-users unless this work is handled by representative offices or registered Russian companies belonging to foreign suppliers. Russian distributors' expertise in reaching key healthcare government officials and major hospital and clinic decision-makers should be considered as an important asset and advantage in developing distribution networks in the country. Effective marketing techniques include participation in major trade shows and professional conferences, advertising in major healthcare magazines, and establishing contacts with major trade and professional associations. Also, it is common to arrange training, site visits, and to sponsor trips to major world medical trade events for practicing doctors.

Registration and certification are complicated and time-consuming procedures and require a permanent presence of the manufacturer or its authorized representative in Moscow. Thus, it is recommended to use the following entities: the manufacturers' representative office or registered Russian company, a consultant or a distributor based in Moscow.

Financing medical equipment deals has always been an important issue. A useful financial option is U.S. Export-Import Bank financing. Overall since 1999, Ex-Im Bank has financed $341.9 million in U.S. medical equipment exports. Recently the bank has launched a new portal designed for Russian business people interested in using its services to do business with American firms and for U.S.-based companies interested in exporting goods and services to Russia at: www.wxim.gov/russia/index.html (English) and www.exim.gov/russia/index-ru.html (Russian).

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Upcoming Trade Shows/events

Zdravookhranenie 2004
November 29 - December 3, 2004
Medical Equipment, Devices, Pharmaceuticals, Food Additives, Medical Technologies
Site: Expocentr on Krasnaya Presnya, Moscow
Web site: www.expocentr.ru

Dental Salon 2005
April 25-28, 2005

Site: Crocus Expo Exhibition Center, Moscow
Web site: www.dental-expo.ru
September 20-23, 2005

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